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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,574	05/25/2006	Luc Grisez	I-2003.022 US	5648

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,574	GRISEZ ET AL.	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10 and 12-21* is/are pending in the application.

4a) Of the above claim(s) *1-8,10,12 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with Group III, claims 13-20 filed on June 9, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election *without* traverse (MPEP § 818.03(a)).

Claims 9 and 11 have been canceled.

Claims 1-8, 10, 12 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 9, 2008 .

Claims 13-20 are under examination.

Specification

2. The use of trademarks, for example, BAYOL®, MARCOL®, DRAKEOL®, page 5, line 15 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Applicant is asked to review the specification for these kinds of informalities and correction is required.

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See for example, page 6, line 27. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicant is asked to review the specification for these kinds of informalities and correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent claim 13 is drawn to a vaccine composition comprising bacteria of the species *Streptococcus phocae* and pharmaceutically acceptable carrier.

The specification teaches the present relates to methods of preparing vaccines comprising *Streptococcus phocae,* vaccines comprising *Streptococcus phocae* and methods of combating comprising *Streptococcus phocae* infections in fish using the *Streptococcus phocae* vaccines (page 1).

The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to infection or disease induction. This demonstration is required to determine "protective immunity".

The instant specification teaches that compositions were prepared comprising *Streptococcus phocae* and used in safety trials (see Examples 2-4). The specification also states that vaccination with a water-based vaccine gives a relative increase in antibody titer of 500% after six weeks, whereas a w/o emulsion vaccine gives a relative increase in antibody titer of 200%. See page 15 and Figures 3-4. The instant specification states:

"Challenge will be done with 1.5x109 CFU of live *Streptococcus phocae*/fish".

See page 14, line 33.

Based on this statement, and the lack of challenge studies, one skilled in the art would *not* conclude that the compositions comprising *Streptococcus phocae* have provided "protective immunity" against *Streptococcus phocae* infections even though an increase in antibody titer was seen after vaccination. Challenge studies are necessary to demonstrate that the claimed vaccine compositions are protective against *Streptococcus phocae*. It would require undue experimentation by one of skill in the art to determine whether the claimed vaccine compositions would be effective in preventing *Streptococcus phocae* infections.

The specification has failed to teach or disclose how the claimed vaccine compositions can be used to protect or prevent *Streptococcus phocae* infections. The state of the art regarding fish vaccines *Streptococcus phocae* is cited below.

Newman et al *(Annal Rev of Fish Disease, pp. 145-185, 1993)* teach that there are some factors that impact the ability of a vaccine to protect fish (page 151, 1st column). These factors include (a) composition of vaccine, (b) the health of the animal being immunized, (c) the quality of the environment, (d) drug treatments, (e) routes of exposure to the antigen, (f) temperature dependence and (g) the impact of smolting (page 151, 1st -2nd columns). Newman et al teaches that many other factors are known to impact the development of protective immunity in fish (page 151, Table 3). Newman et al teach that these factor include (a) husbandry, (b) handling, (c) age, (d) smoltification, (e) dominance hierachies, (f) pheromones , (g) temperature, (h) diet, (i) pollutants, (j) seasonal variations, (k) vaccine related factors, (l) dose and nature of immunizing antigens, (m) route of administration, (n) immunostimulants, (o) diseases and (p) antibiotics (page 151, Table 3). Newman et al teach that infection due to *Streptococcus* species causes losses in the fish industry annually (page 175). Newman et al disclose Table 28, which shows characteristics and properties of the *Streptococcus* species that infect fish (page 175). Skaar et al *(International Journal of Systemic Bacteriology, Oct. 1994, p. 646-650)* teach a new species of *Streptococcus, Streptococcus phocae* (see the Abstract and the Title). Skaar et al teach that *Streptococcus phocae* is beta-hemolytic and was isolated from seals (see the Abstract). Henton et al *(Tydskr. S.Aft.vet.Ver.(1999), 70(2):98-99)* teach that *Streptococcus phocae* infections are associated with starvation in seals (see Title and the Abstract). Henton et al that *Streptococcus phocae* was present in these seals as a secondary opportunist (page 99, 2nd column).

The cited prior art references indicate that there are many factors that impact the ability of a vaccine to protect fish as well as impact the development of protective immunity in fish. The prior art references also indicate that *Streptococcus* species cause infections in fish and *Streptococcus phocae* is new species of the genus *Streptococcus*. However, there is no vaccine composition to protect against *Streptococcus phocae* infections.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to developing a vaccine composition that provides protective immunity against infections caused by *Streptococcus phocae*, 3) there are no working examples which teach or suggest that the composition comprising *Streptococcus phocae* disclosed in the instant specification provides protective immunity, 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level) and cited prior art has taught factors that

impact the ability of a vaccine to protect fish as well as impact the development of protective immunity in fish.

In view of all of the above, it is determined that the specification has not provided guidance that would enable one of skill in the art to be able to make and use the claimed invention commensurate with the claims. One of skill in the art would require undue experimentation to determine whether the claimed vaccine compositions could be used to prevent infections caused by *Streptococcus phocae* because the specification has not disclosed challenge studies that provide substantive evidence that the compositions comprising *Streptococcus phocae* can protect against *Streptococcus phocae* infections in fish.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by Henton et al *(Tydskr. S.Aft.vet.Ver.(1999), 70(2):98-99).*

Independent claim 13 is drawn to a vaccine composition comprising bacteria of the species *Streptococcus phocae* and pharmaceutically acceptable carrier.

Dependent claim 19 is drawn to the vaccine according to claim 13, wherein the vaccine is in a freeze-dried form.

Henton et al teach compositions comprising the bacteria of the species *Streptococcus phocae* grown in liquid medium (page 99). The instant specification teaches that the vaccine compositions of the invention were prepared in medium and the bacterial cells were resuspended in culture supernatant. Fish were injected using 1 ml of the vaccine composition formulated in PBS. See pages 12-13, Example 3. Thus, the vaccine composition of the invention comprise culture medium as a pharmaceutically acceptable carrier. The claim limitation "vaccine" is being viewed as a limitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The claim limitation "...wherein the vaccine is in a freeze-dried form" is being viewed as a process limitation in a product claim. Although the reference appears to disclose vaccine compositions comprising the species of bacteria, *Streptococcus phocae* claimed by the applicant's, the reference does not disclose the vaccine composition in the freeze-dried form. However, the production of the vaccine composition by a particular process does not impart novelty or unobviousness to a vaccine composition when the same vaccine composition is taught by the prior art. This is particularly true when the properties of the vaccine composition are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC

1985); In re Marsosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Since the Office does not have the facilities for examining and comparing applicant's vaccine composition with the vaccine composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine composition of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

6. No claims allowed.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/

Patent Examiner, Art Unit 1645